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*ADMITTED IN DC ONLY

June 4, 2018

Re: *UMB Bank, N.A., as Trustee* v. *Sanofi*, 15 Civ. 8725 (S.D.N.Y.) (GBD) (RWL)

Dear Magistrate Judge Lehrburger:

Plaintiff UMB Bank, N.A., as Trustee, seeks to compel production of a small set of post-July 2016 documents that have recently come to our attention. This motion is consistent with the Court's ruling that "efforts undertaken by Sanofi during 2017 may well serve as a benchmark against which to measure efforts made during 2016 as an example." November 16, 2017 Hearing Transcript at 34.[1]

On May 8, 2018, Carole Huntsman (the North America Head of Multiple Sclerosis, Oncology and Immunology at Genzyme) [redacted] in January of 2018, Sanofi stated that "it plans to build on the proven long-term clinical profile of Lemtrada® (alemtuzumab) by initiating a Phase 3 study in 2018 in patients with Primary Progressive Multiple Sclerosis (PPMS)."[2] Huntsman testified [redacted]

[1] On May 8, 2018, the Trustee inquired whether Sanofi would produce any of the PPMS related documents covered by this motion. On May 22, 2018, after a telephonic meet and confer, Sanofi indicated it was considering the matter. The same day, the Trustee specified via email which categories of documents it was entitled to. On May 23, 2018, by email, Sanofi rejected the Trustee's specific proposal, but indicated that it was still considering the matter generally. On May 30th, Trustee again asked if any of the requested documents would be produced and offered to discuss whether a further narrowing of the scope of the request might change that decision. No answer has been received.

[2] *See* Sanofi January 2018 Letter to Shareholders, Declaration of Michael B. Weiss, Esq. ("Weiss Decl."), Ex. A, at 5; *see also* [redacted] Weiss Decl., Ex. B at 223:11-224:24. Complete copies of excerpted material are available upon request.

[redacted][3] None of these documents have been produced in discovery in this action.

Plaintiff seeks documents relating to the decision to commence a PPMS trial with Lemtrada® on the grounds that, consistent with the Court's prior rulings, the decision to move forward with this trial in 2018 is probative to determining why—[redacted]—Sanofi refused to fund such a study earlier as part of its CVR Agreement obligation to use Diligent Efforts to achieve the Lemtrada Product Approval and Product Sales Milestones.

Lemtrada® is an anti-CD52 antibody approved for Relapsing and Remitting Multiple Sclerosis ("RRMS"). RRMS is the most common form of MS. Other forms of MS, however, are clinically significant. PPMS is recognized by the FDA, MS community and the pharmaceutical industry as a high unmet need.[4]

Discovery in this case has shown that as of the date of the CVR Agreement [redacted][5]

[redacted]

[redacted]

[redacted]

[3] *See* Huntsman Dep. at 225:10-16.

[4] Ocrevus® (ocrelizumab), an anti-CD20 antibody indicated for the treatment of PPMS, was approved in March of 2017. Weiss Decl., Ex. C (Press Release, Food and Drug Administration, FDA Approves New Drug to Treat Multiple Sclerosis). Ocrevus received both Fast Track and Priority Review status which shortens the amount of time it takes the FDA to review an application. *Id.* Had Lemtrada® received Fast Track and Priority Review status, the Trustee believes that it would have greatly increased the likelihood of achieving the FDA Approval Milestone and Product Sales Milestone #1.

[5] [redacted]

[6] [redacted]

[redacted]

Efforts over the ensuing years to revive the PPMS study failed [redacted]

Instead of diligently developing Lemtrada® for PPMS, Sanofi initially considered developing another anti-CD52 antibody named GLD52 in PPMS.[7] Internal estimates prepared by Genzyme show that an anti-CD52 antibody active in PPMS could be worth tens of billions of dollars, with annual peak sales forecast between €1.69 and €2.8 Billion. *See* Weiss Decl., Ex. F at SAN-CVR 018728942. Tellingly, these estimates show that Sanofi planned that this revenue would be earned **after** the termination of the CVR Agreement in 2020. *Id.*

[redacted]. In other words, when enough time had passed so that Sanofi could develop Lemtrada® without concern of having to make payments to the CVR Holders, it commissioned the study it should have done all along. Ms. Huntsman testified that [redacted]

It is the Trustee's contention that had Sanofi timely undertaken such a trial it would have achieved the Lemtrada Product Approval Milestone and Product Sales Milestone #1. At a minimum, the Trustee is entitled to know why the management of Sanofi has withheld Lemtrada® from PPMS patients for at least seven years.

Trustee believes it is entitled to documents relating to [redacted] Trustee believes that this universe of documents is limited and seeks such an order.

[7] GLD52, like Lemtrada, is an anti-CD52 antibody discovered by Genzyme.

Respectfully submitted,

Michael B. Weiss

Hon. Robert W. Lehrburger
United States Magistrate Judge
Southern District of New York
500 Pearl Street
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Via ECF, Email, and Hand Delivery

cc: Counsel of Record